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5.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

The submitter of this premarket notification is:
Michael Asmalsky
Philips Medizin Systeme Boeblingen GmbH
Hewlett-Packard-Str. 2
D-71034 Boeblingen, Germany

Tel: +49 7031 463-1277 Fax: +49 7031 463-2442
Email: michael.asmalsky@philips.com

This summary was prepared on June 26th, 2007.

5.1 Device Names

The names of the devices are the Philips Avalon Fetal Monitors FM20 and FM30. Classification names are as follows.

Device Panel	Classification	ProCode	Description
Obstetrical and Gynecological Monitoring Devices	§884.2660, II	MAA HEL HEK KNG	Fetal ultrasonic monitor and accessories
	§884.2675, II	HGP	Fetal scalp circular (spiral) electrode and applicator
	§884.2700, II	HGS KXO HFO HFN	Intrauterine pressure monitor and accessories
	§884.2720, II	HFM	External uterine contraction monitor and accessories
	§884.2740, II	HGM	Perinatal monitoring system and accessories
	§884.2960, II	HGL	Obstetric ultrasonic transducer and accessories
Circulatory System Devices	§870.1100, II	DSJ	Alarm, Blood Pressure
	§870.1110, II	DSK	Computer, Blood Pressure
	§870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	§870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	§870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	§870.2340, II	DPS	Electrocardiograph
	§870.2600, I	DRJ	System, Signal Isolation
	§870.2700, II	DQA	Oximeter
	§870.2810, I	DSF	Recorder, Paper Chart
	§870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector

5.2 Subject devices	The subject devices Philips Avalon Fetal Monitors FM20 and FM30 are substantially equivalent to previously cleared Philips Avalon Fetal Monitors FM20 and FM30 marketed pursuant to K052795 and K062137.
5.3 Modifications	The modification of the Philips Avalon Fetal Monitors FM20 and FM30 only introduces the capability for healthcare professionals of monitoring pregnant women at private households

5.4 Intended Use

Excluding the added intended use location of private households, the intended use is the same as previously cleared for the legally marketed predicate device Philips Avalon Fetal Monitors FM20(M2702A)and FM30(M2703A)(K052795 and K062137).

The Philips Avalon FM20 (M2702A), FM30 (M2703A), Fetal/Maternal Monitors are intended for non-invasive monitoring of the physiological parameters of pregnant women during antepartum testing and labor and delivery. The FM30 is additionally intended for invasive monitoring.

All monitors are intended for monitoring fetal and maternal heart rates, uterine activity, maternal noninvasive blood pressure, and additionally for the FM30, oxygen saturation (SpO2).

All monitors are intended for generating alarms from fetal and maternal parameters, for displaying, storing and recording patient data and related waves, transmitting patient data to a patient information and surveillance system on a network, and for postpartum monitoring of the mother.

All monitors are intended for use by trained health care professionals.

They are intended for use in labor and delivery rooms, antepartum testing areas and during postpartum recovery in the hospital environment.

They are not intended for use in intensive care units or operating rooms. The FM20 and FM30 are additionally intended for use in healthcare facilities outside hospitals, for example in doctors' offices, and for home use.

Contraindications: All monitors are NOT intended for:
- use during defibrillation, electro-surgery, or magnetic resonance imaging (MRI).
- ECG measurements on patients connected to external electrical stimulators or with cardiac pacemakers.
- use with the IUP/ECG patient module (M2738A) in domestic establishments and those connected directly to the public low-voltage supply network that supplies buildings used for domestic purposes.

5.5 Technological Characteristics

The subject devices Philips Avalon Fetal Monitors FM20 and FM30 have the same technological characteristics as the legally marketed predicate devices Avalon Fetal Monitors FM20 and FM30.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 27 2007

Mr. Michael Asmalsky
Regulatory Affairs Engineer
Philips Medizin Systeme Boblingen GmbH
Ultrasound and Monitoring – Patient Monitoring
Hewlett-Packard Str.2, D-71034 Boeblingen, Germany

Re: K071800
Trade Name: Phillips Avalon Fetal Monitors FM20 (M2702A) and FM30 (M2073A)
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: June 26, 2007
Received: July 2, 2007

Dear Mr. Asmalsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: Philips Avalon Fetal Monitors
FM20(M2702A) and FM30(M2703A).

Indications for Use:

Avalon Fetal Monitor FM20:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, non-invasive blood pressure, pulse rate of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms, in antepartum testing areas and in private households.

Avalon Fetal Monitor FM30:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, ECG, oxygen saturation, non-invasive blood pressure, and pulse rate of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms, in antepartum testing areas and in private households.

Prescription Use __Yes_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __No___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071807